



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/567,114

02/03/2006

Valery Khazhmuratovich Zhilov

4874-7000

2900

27123 7590 09/23/2008
MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

09/23/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com
Shopkins@Morganfinnegan.com
jmedina@Morganfinnegan.com

Office Action Summary	Application No. 10/567,114	Applicant(s) ZHILOV ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 43-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Previous Office Action Vacated

The Office Action mailed 19 Aug 2008 is **vacated**. The Office Action mailed 19 Aug 2008 was directed to the claims filed on 08 Aug 2006. However, a phone conversation on 25 Aug 2008 with Applicant's representative, Matthew Eggerding, clarified the pending claims as the claims of the preliminary amendment filed 03 Feb 2006, distinguished by the identification as the National Phase Application of PCT/RU2003/000346 with Docket No. 4874-7000. The document filed on 08 Aug 2006 correspond to the claims of the related case identified as the National Phase Application of PCT/RU2003/000298 with Docket No. 4874-7001, submitted in the IDS mailed 08 Aug 2006.

This Office Action details a Restriction Requirement and an Election of Species Requirement.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical

Art Unit: 1623

features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

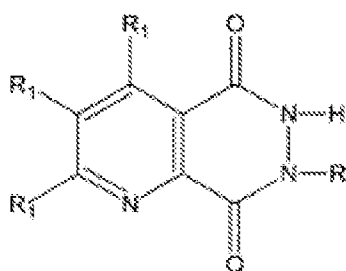
Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restriction Requirement

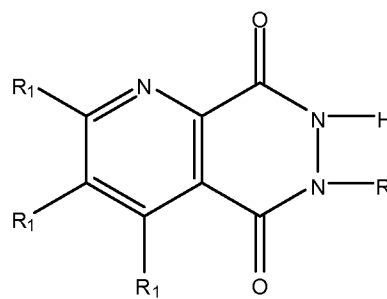
Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 44-45, and 43 and 56-70 in part, drawn to a compound having the

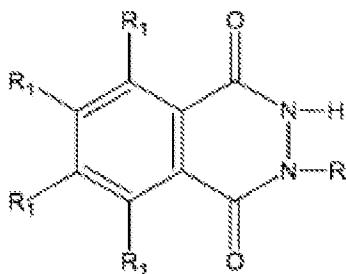


general formula



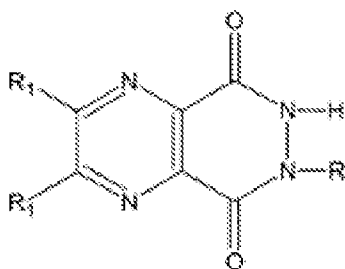
or

Group II, claim(s) 46-47, and 43 and 56-70 in part, drawn to a compound having the



general formula

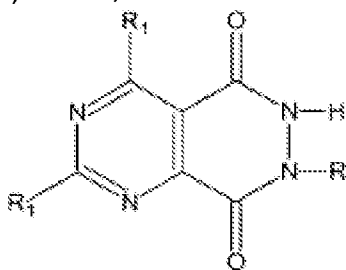
Group III, claim(s) 48-49, and 43 and 56-70 in part, drawn to a compound having the



general formula

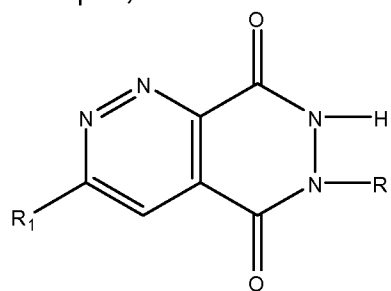
Art Unit: 1623

Group IV, claim(s) 50-51, and 43 and 56-70 in part, drawn to a compound having the

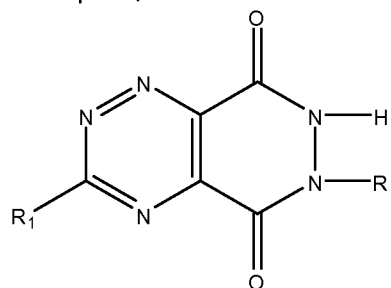


general formula

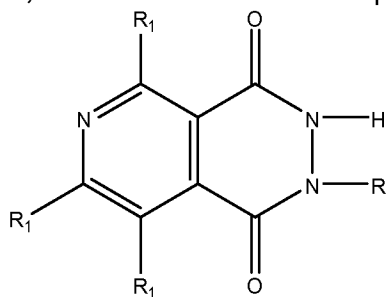
Group V, claims 43 and 56-70 in part, drawn to a compound having the general formula



Group VI, claims 43 and 56-70 in part, drawn to a compound having the general formula



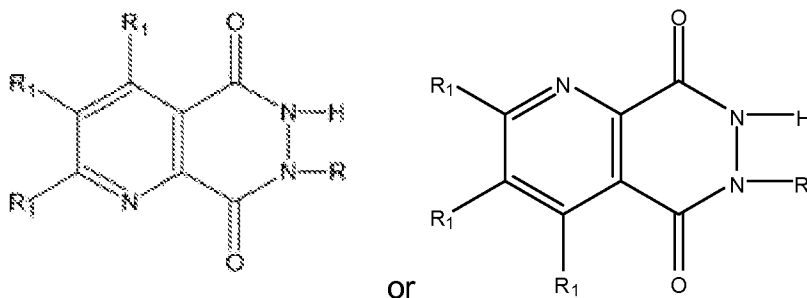
Group VII, claims 43 and 56-70 in part, drawn to a compound having the general



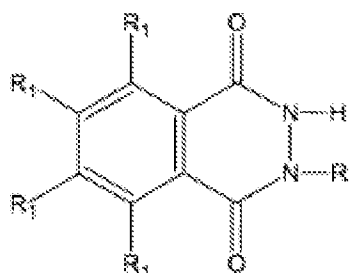
formula

Art Unit: 1623

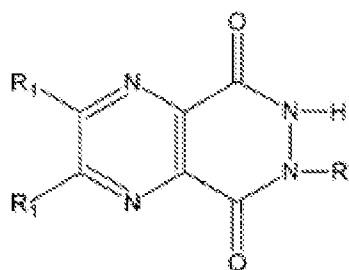
Group VIII, claim(s) 52-55 in part, drawn to a method comprising administering a therapeutically amount of a compound having the general formula



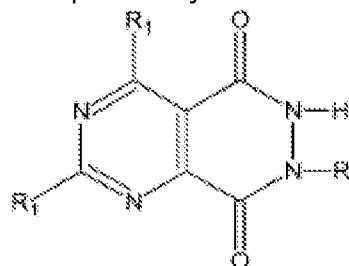
Group IX, claim(s) 52-55 in part, drawn to a method comprising administering a therapeutically amount of a compound having the general formula



Group X, claim(s) 52-55 in part, drawn to a method comprising administering a therapeutically amount of a compound having the general formula

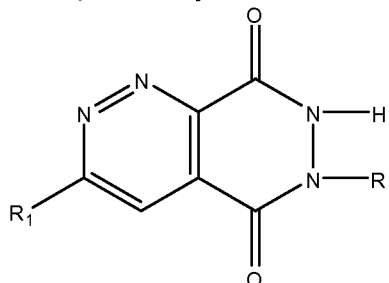


Group XI, claim(s) 52-55 in part, drawn to a method comprising administering a therapeutically amount of a compound having the general formula

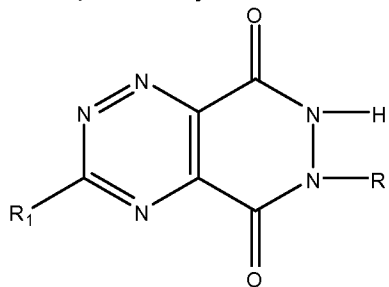


Art Unit: 1623

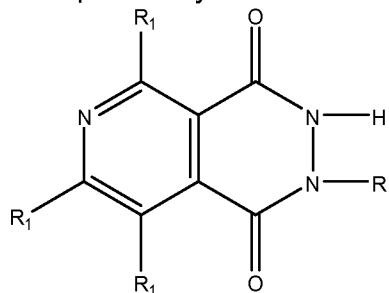
Group XII, claim(s) 52-55 in part, drawn to a method comprising administering a therapeutically amount of a compound having the general formula



Group XIII, claim(s) 52-55 in part, drawn to a method comprising administering a therapeutically amount of a compound having the general formula

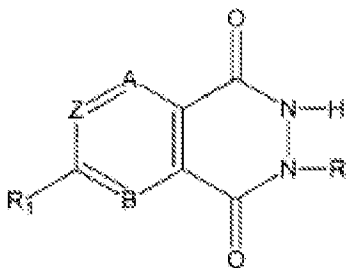


Group XIV, claim(s) 52-55 in part, drawn to a method comprising administering a therapeutically amount of a compound having the general formula



The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-XIV lack unity of invention because even though the inventions of these groups require the technical feature of a compound of general formula



disclosed in claim 43, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Minin et al. (United States Patent 5,512,573, issued 30 Apr 1996, cited in PTO-892). Minin et al. discloses the sodium salt of 5-aminophthaloylhydrazide (column 5, lines 20-30 and column 10, claim 1), a compound of the general formula. Therefore this shared feature does not constitute a special technical feature over the prior art.

Where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity; AND

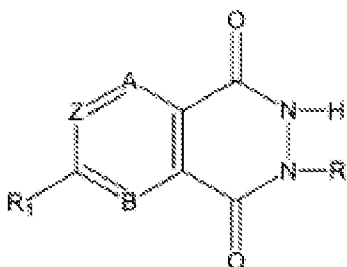
(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

The phrase “significant structural element is shared by all of the alternatives” refers to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity.

The phrase “recognized class of chemical compounds” means that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention, i.e. each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Although the chemical compounds of Groups I-XIV share a common structure of



, the common structure is not a significant structural element because it represents only a small portion of the compound structures and does not constitute a structurally distinctive portion in view of Minin et al., which discloses the sodium salt of 5-aminophthaloylhydrazide (column 5, lines 20-30 and column 10, claim 1), a compound according to Group II and IX. Further, the compounds of these groups do not belong to a recognized class of chemical compounds. The alternatives do not all

belong to a recognized class of chemical compounds of either a pyrido[2,3-d]-6H-pyridazine (Group I and VIII), benzo[d]pyridazine (Group II and IX), pyrazino[2,3-d]-6H-pyridazine (Group III and X), pyrimido[4,5-d]-6H-pyridazine (Group IV and XI), pyridazino[3,4-d]-6H-pyridazine (Group V and XII), triazino[5,6-d]-6H-pyridazine (Group VI and XIII), and pyrido[3,4-d]-6H-pyridazine (Group VII and XIV). These different core structures belong to different classes of chemical compounds, such as benzo[d]pyridazine, which is a bicyclic compound containing two heteratoms, and triazino[5,6-d]-6H-pyridazine, which is a bicyclic compound containing 5 heteroatoms and a [5,6-d] bicyclic ring fusion.

Election of Species Requirement

This application contains claims directed to more than one species of compound for each generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Examples of a species of compound of the general formula are as follows:

sodium salt of pyrido[2,3-d]-6H-pyridazine-5,8-dione, a species of the invention of Group I and VIII, disclosed in claim 45,

sodium salt of 2-(β -D-ribofuranosyl)benzo[d]-3H-pyridazine-1,4-dione, a species of the invention of Group II and IX, disclosed in claim 47, and

sodium salt of 2-amino-7-(β -D-ribofuranosyl)pyrazine[2,3-d]-6H-pyridazine-5,8-dione, a species of the invention of Group III and X, disclosed in claim 49.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic:

All claims are generic to the species of compound.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If

Art Unit: 1623

claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

Art Unit: 1623

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner
Art Unit 1623